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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/122,384	07/24/98	ELLEGE	BCM-03434

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HM12/0416

EXAMINER

RAILEY, J

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/16/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	12

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application
Commissioner of Patents

Office Action Summary

Application No.

09/122,384

Applicant(s)

Elledge et al.

Examiner

J. Railey

Group Art Unit

1636



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-36 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, 26 and 30-35, drawn to methods of *in vitro* and *in vivo* recombination of nucleic acid constructs using a site-specific recombinase, or sequence-specific recombinase, and host cells comprising nucleic acids used in the methods, classified in class 435, subclass 471.
- II. Claims 22-25, drawn to methods for recombination of nucleic acids in an *E. coli* host cell using an "endogenous recombination system" such claims not specifically requiring use of a "site-specific recombinase," classified in class 435, subclass 476.
- III. Claims 21 and 36, drawn to a recombined nucleic acid construct prepared *in vitro*, classified in class 536, subclass 22.1.
- IV. Claim 27, drawn to a nucleic acid library, classified in class 435, subclass 320.1.
- V. Claims 28 and 29, drawn to methods for directional cloning, the methods neither involving use of host cells nor recombinase, classified in class 435, subclass 91.1.

The inventions are distinct, each from the other because:

Inventions of Groups I, II and V are independent and distinct methods in the art for

subcloning or manipulating nucleic acids which are unrelated in function and operation. The method of Group I uses a site-specific recombinase and a specific site to allow joining of two nucleic acid molecules either *in vitro* or within cells *in vivo*. The method of Group II uses a host cell's "endogenous recombination system" for subcloning and does not involve a "site-specific recombinase." This method can be simple recombination between two nucleic acid molecules at homologous regions and is not related in function or operation to the method of Group I. The method of Group V involves a simple procedure of inserting one nucleic acid into another *in vitro* and can be simple restriction and ligation of the two molecules. This is unrelated in function or effect to the methods as found in either of Group I or II.

Inventions of Group I and either one of Group III or IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by other methods, such as restriction and ligation of nucleic acid elements *in vitro* without the use of a site-specific recombinase.

The methods of either of Group II or V are not used to make the product of Group III or Group IV.

Inventions of Group III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to distinct nucleic acid molecules in the art, each unrelated to the other. The nucleic acid molecules of Group I are each comprised of the same molecular insert, while the library of Group IV is inherently comprised of different nucleic acid molecular inserts. Therefore, each nucleic acid product of Groups III and IV are unrelated chemically.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. In addition, the searches for each of the Groups are not commensurate in the art.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technology Center 1600 by facsimile

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Art Unit: 1636

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transmission. Papers should be faxed to Art Unit 1636 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for Art Unit 1636 is (703) 308-4242 or 305-3014.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. F. Railey, whose telephone number is (703) 308-0281. The examiner can normally be reached on Monday-Thursday, and alternate Fridays, from 8:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax phone number for informal transmissions to the examiner is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15 April 1999

**JOHNNY F. RAILEY II, PH.D.
PRIMARY EXAMINER
TECHNOLOGY CENTER 1600**

A handwritten signature in black ink, appearing to read "John F. Railey II", written in a cursive style.